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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE PACIFIC FERTILITY CENTER LITIGATION

Case No. 3:18-cv-01586-JSC

DEFENDANT CHART INC.'S REPLY IN SUPPORT OF ITS MOTIONS TO EXCLUDE ANAND KASBEKAR, DAVID WININGER, AND ELIZABETH GRILL

Date: March 4, 2021
Time: 9:00 a.m.
Judge: Hon. Jacqueline Scott Corley
Place: Zoom

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INTRODUCTION

In its Motions to Exclude Plaintiffs' experts Anand Kasbekar, David Wininger, and Elizabeth Grill, Chart demonstrated that the experts are unqualified to assert certain conclusions and said conclusions lack reliable methodology. Specifically, Kasbekar, as an engineer with metallurgy experience, is unqualified to opine on cryogenics. Kasbekar's causation opinion is unreliable as he failed to perform any testing to validate his hypothesis, and his attempt bolster is defect opinion with a flawed and untimely Finite Element Analysis (FEA) is improper. Wininger is unqualified to offer testimony as to the expectations of an ordinary user given his lack of experience with computer controlled cryogenic tanks. Wininger's opinions are unreliable as he failed to consider key facts and irrelevant because the consumer expectations test is not applicable to the sophisticated, complex product at issue. Grill is unqualified to offer a damages opinion because she has no training or experience in forensic psychology. And, finally, Grill's opinions are wholly unreliable as her brief evaluations of Plaintiffs fail to comply with the standard of care in both forensic and clinical psychology.

Plaintiffs' response arguments do not cure these deficiencies. First, Plaintiffs concede the main points of Chart's argument concerning the experts' lack of qualifications. For example, Plaintiffs' do not dispute that Kasbekar lacks cryogenic experience and training and that he did not perform key testing; Wininger does not have experience with computer controlled tanks; and Grill is not a forensic psychologist. Plaintiffs further concede several key components of Chart's argument concerning the experts' unreliable methodology. For example, Plaintiffs' admit that Wininger did not consider PFC embryologists' actions in forming his user's expectations opinion and Grill did not perform any objective testing.

Chart respectfully requests that the Court exclude Anand Kasbekar, David Wininger, and Elizabeth Grill.

ARGUMENT

I. KASBEKAR'S CAUSATION OPINION AND UNTIMELY FEA SHOULD BE EXCLUDED.

There is no dispute Plaintiffs must establish by a preponderance that Anand Kasbekar (1) is qualified to render expert opinions on the specific issues in this case and (2) offers a reliable causation opinion based on sound methodology that passes *Daubert* / Rule 702 scrutiny. The legal inadequacy of Plaintiffs' response is underscored by the facts, propositions, and legal authorities that Plaintiffs ***cannot*** or ***do not*** even attempt to refute:

- That Kasbekar, an engineer with metallurgy experience, lacks cryogenic experience and training for the specific issues of this case;
- That Kasbekar's causation opinion is not supported by any scientific testing to validate his hypothesis that 14 inches of liquid nitrogen (LN2) was lost in Tank 4 in less than 24 hours; and
- That Rule 702 and *Daubert* require exclusion of a plaintiff's expert's causation opinion not supported by testing to validate the opinion, where the opinion is nothing more than *ipse dixit* speculation of what could have occurred.

Rather than address these fundamental issues head-on, Plaintiffs resort to (1) comparing Kasbekar to Chart's experts and (2) reiterating Kasbekar's metallurgy credentials and that he should be able to explain to a jury his metallurgy-based opinion that Tank 4 contains a fractured weld. But Chart's attack on Kasbekar is focused on incident ***causation*** and his lack of credentials and testing on cryogenic issues that are central to his causation opinion. His causation opinion rests on untested assumptions, which fail the *Daubert* standard for admissibility.

In many respects, Plaintiffs' Opposition Brief and the gravamen of Chart's *Daubert* Motion are like two ships passing in the night. Plaintiffs all but ignore Kasbekar's guesswork on cryogenics and results-oriented "say-so" as to the cause of Plaintiffs' damages. Kasbekar's causation opinion should be barred.

A. Kasbekar is not qualified to give opinions on the cryogenic issues that are central to his causation opinion.

According to Plaintiffs, because Kasbekar is a professional expert that has testified in many other cases using his general engineering background, he is therefore qualified to render a broad array of opinions in this case, including for the lynchpin of his causation opinion: the rate of LN2 consumption in a cryogenic tank with an allegedly compromised vacuum seal. First and foremost, Kasbekar's experience in testifying in other cases on different subject matters is simply not a competent basis for qualifying him in this action. *Cf. Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 800 (4th Cir. 1989) *cert denied*, 493 U.S. 1073 ("Although it would be incorrect to conclude that [the expert's] occupation as a professional expert alone requires exclusion of her testimony, it would be absurd to conclude that one can become an expert simply by accumulating experience in testifying.").

Plaintiffs devote much of their brief to comparing Kasbekar to Chart's metallurgy expert, Ron Parrington. But this argument has an obvious problem: Chart is not attacking Kasbekar's metallurgy credentials. Instead, Chart's attack is focused on Kasbekar's lack of cryogenic qualifications, which is the specific area of this case where Kasbekar ventured to provide a causation opinion.[1] Kasbekar's causation theory includes two parts (*i.e.*, two hypotheses). First, that Tank 4 had a crack in a weld that was progressive and induced by stress. And, second, that LN2 boiled-off (evaporated) from Tank 4 rapidly (in less than 24 hours) due to the weld crack.

While Chart did not challenge Kasbekar's metallurgy qualifications, that alone does not mean Kasbekar is qualified for this case. Chart is challenging Kasbekar's qualifications to opine on the second part of his causation opinion—that LN2 rapidly escaped and boiled-off as Tank 4 warmed and, as a result, Plaintiffs' tissue was damaged (*i.e.*, incident causation). Plaintiffs cannot dispute Kasbekar's opinion that any alleged defect in Tank 4 ***caused*** damage to Plaintiffs' tissue rests on the following cryogenic hypotheses:

[1] Indeed, when necessary for foundational purposes, Parrington relied on Dr. Franklin Miller's cryogenic analysis, rather than venture into the cryogenic issues on his own like Kasbekar did. So if comparisons are to be made, then Kasbekar should not opine on cryogenic issues either. The problem for Plaintiffs is that that would mean they have no expert on a key element of their product liability case against Chart—causation.

(1) The LN2 boil-off rate of Tank 4 with a compromised vacuum seal must cause 14 inches of LN2 to boil-off in less than 24 hours, leaving the Plaintiffs' tissue damaged; and

(2) The visual appearance of Tank 4 with a compromised vacuum seal during the boil-off period must look as described by PFC personnel.

Because Plaintiffs cannot credibly say Kasbekar is qualified to testify on these specific issues, they didn't. Instead, Plaintiffs summed up Kasbekar's qualifications (or lack thereof) in one sentence: "Kasbekar has worked with cryogenic tanks before as well and had previously evaluated a failed cryogenic tank before this litigation." (Pls.' Opp. at 15). In support of that proposition, Plaintiffs cite to pages 71 through 78 of his deposition. But that swath of deposition testimony only serves to underscore Kasbekar has no business testifying to a jury as an "expert" on cryogenic issues. For example, the suggestion that Kasbekar is qualified because he has "done general reading at the beginning of this case related to cryogenic vessels" boarders on absurd. (Ringel Decl. Supp. Mot. Exclude Kasbekar, Ex. D ("Kasbekar Depo II") at 71:9-10, ECF No. 647.10).

With respect to LN2 boil-off rates, Kasbekar admits he is no more helpful to a jury than a college graduate student who understands that cryogenic tanks need to stay really cold to safely store their contents. But the causation issue in this case is significantly more nuanced. It is about timing; when did Tank 4 run out of LN2? Yet that is where Kasbekar's experience is non-existent. When questioned on whether he had "personally ever witnessed a cryogenic dewar like tank 4 lose vacuum seal with liquid nitrogen inside [,]" Kasbekar pointed to his graduate student experience and confirmed he knew nothing on the subject:

> I am going to answer it this way. As a graduate student, I have seen cryogenic storage vessels that have lost vacuum with nitrogen inside. ***But whether that happened over minutes or hours, I don't know.*** I have just seen the net effect of that happening, and we've had to replace those vessels and get new vessels in.

(Kasbekar Dep. II at 71:20-72:1, ECF No. 647.10) (emphasis added). When questioned further about the tank that had lost vacuum seal and needed replacement, and specifically "how long it took for that failure to occur[,]" Kasbekar said, "I have no idea. I remember us coming across it

one day, and it was remarkable." (Kasbekar Dep. II at 76:10-13, ECF No. 647.10).

With respect to the visual appearance of cryogenic tanks with vacuum seal failures, Kasbekar also pointed to his experience in college. But when pressed to explain the appearance of a tank with a loss of vacuum seal, he could only provide vague recollections of events from more than 30 years ago: "I suspect that there was moisture but, honestly, I have an image of the tank and the frost on the outside, and I don't have an image of what was happening on the floor." (Kasbekar Dep. II at 76:14-77:7, ECF No. 647.10). In sum, hanging around cryogenic tanks in college falls far short of satisfying Rule 702. This does not equate to possessing the necessary "knowledge, skill, experience, training, or education" to testify in federal court as an expert regarding when and how quickly Tank 4 ran out of LN2 so as to have caused damage to Plaintiffs' tissue. *Daubert* demands more and so does this case.

B. Kasbekar's causation opinion is not supported by testing and is therefore unreliable and inadmissible under *Daubert*.

Plaintiffs' arguments about Kasbekar's failure to test his theory largely side-step the issue. That Kasbekar is not a cryogenic engineer is not, by itself, fatal to the admissibility of his causation opinion under *Daubert*. Indeed, experts, especially engineers, are permitted to study new products, perform experiments using the scientific method, and test hypotheses to form reliable and admissible opinions. Here, the product is an MVE 808 tank that used LN2 to preserve and store items at cryogenic temperatures (approximately -196C). Plaintiffs do not dispute that scientific experimentation is the foundation of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993) ("a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. 'Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.'"). But Kasbekar's lack of experience with cryogenic vessels means that he, of all of the experts in this case, should have completed testing and experimentation to determine how LN2 performs inside of an MVE 808 tank with and without a vacuum seal loss. Such testing

was necessary to validate his ultimate opinion that any alleged defect actually caused Plaintiffs' damages. He did not do that work.

Rather, in blind reliance on PFC employee testimony, Kasbekar assumed a high boil-off rate occurred as a result of a theoretical pre-incident crack in the fill port weld. Specifically, Kasbekar based this assumption on Jean Popwell's testimony that she measured 14 inches of LN2 in Tank 4 on the afternoon of March 3, 2018 and Dr. Conaghan's testimony that the LN2 measured less than 1 inch after noon on March 4, 2018. Thus, for Ms. Popwell's purported 14 inch measurement, and by extension Kasbekar's causation opinion, to be valid, 14 inches of LN2 had to evaporate from Tank 4 in less than 24 hours (to be more precise, 22 hours). There must also be an absence of visual indicators of vacuum seal failure during the boil-off period. Plaintiffs' excuse for Kasbekar's failure to test these critical cryogenic-based hypotheses is Kasbekar's own testimony that such tests cannot be completed. (Pls.' Opp. at 18). This is nothing more than classic, inadmissible *ipse dixit*.[2] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

If anything, Kasbekar's own testimony undercuts Plaintiffs' argument that testing could not be completed. Kasbekar had access to an exemplar MVE 808 tank, but he never bothered to fill it with LN2 or test it with a fully compromised vacuum seal. Yet that is what he claims occurred here. When questioned at his deposition about why he did not conduct any such testing on the exemplar, Kasbekar's answer is tailor-made for a *Daubert* ruling excluding him from this case:

> Q: Let's say you have an exemplar MVE 808, and you through your analysis recreate the crack in the weld at issue, and you filled up the freezer with 14 inches of liquid nitrogen. What would you expect that test to show?
>
> . . .
>
> A: I would expect it to show an increase evaporation rate of the nitrogen. I would expect it to eventually show, because of a loss of vacuum, condensation and frost build-up on the exterior of the tank. And then I would expect ***over some period of time*** that if sufficient nitrogen were to enter into the vacuum space and you were to allow the remaining nitrogen in the tank to evaporate off that you would have a buckling of the tank.

[2] From Latin, this phrase is translated "he himself said it." An *ipse dixit* statement is one which is unsupported and rests solely on the authority of the individual who makes it. *See* https://thelawdictionary.org/ipse-dixit/ (last visited Feb. 9, 2021).

Q: Do you have any plans to run that type of an experiment on the exemplar that you currently have access to?

A: I do not.

(Kasbekar Dep. II at 35:13-36:7, ECF No. 647.10). Perhaps unwittingly, Kasbekar identified this event would take place "over some period of time," which is the timing question that required scientific experimentation to understand and validate the causation opinion he proffered. Kasbekar identified the issues and his "expectations" (*i.e.*, hypotheses), but decided to not actually test the validity or falsehood. This is a text book example of an expert offering a causation opinion that falls short of the *Daubert* standard.

Dow v. Rheem Mfg. Co., 527 F. App'x 434 (6th Cir. 2013), illustrates this point. In *Dow*, the plaintiff's expert had a two-part (two-hypothesis) causation theory. The first part was supported by sufficient testing and analysis. However, the expert admitted he did not test the second part of his theory, stating: "Given the number of variables involved, I don't think, even with testing, you can duplicate the—you know, the exact conditions on every valve." *Id*. at 437. The court excluded the expert's causation opinion because it was unreliable without testing to validate the second part (hypothesis) of the theory.

District courts in the Ninth Circuit have reached similar conclusions. *See Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1157 (D. Mont. 1999) (excluding expert's causation opinion where expert admitted his opinion was "simply a hypothesis which has not been tested and may be impossible to test" because the opinion therefore "lack[ed] the rigor imposed by scientific methodology" and did not "have the evidentiary reliability to be admissible" under Rules 702 and 703); *Lucido v. Nestle Purina Petcare Co.*, 217 F. Supp. 3d 1098, 1112 (N.D. Cal. 2016) (precluding expert physician from opining on causation where expert did not conduct any tests related to his causation opinion, and relied on scientific literature that was either too speculative or too imprecise to support his causation opinion); *Johnson v. Am. Honda Motor Co.*, 923 F. Supp. 2d 1269, 1274 (D. Mont. 2013) (excluding expert's opinion because, "[b]y his own admission, [the expert] never tested his theory"). The result here should be no different.

Unlike Kasbekar, Dr. Miller knew how to and did complete testing of his cryogenically-based hypotheses. First, based on his vast experience with cryogenic vessels, Dr. Miller knew that

even with a completely compromised vacuum seal, the LN2 boil-off rate for cryogenic tanks with multilayer vacuum insulation systems (*i.e.*, the MVE 808) is relatively low. He also knew that this was likely inconsistent with the high boil-off rate that Kasbekar assumed occurred here as a result of a theoretical pre-incident crack in the fill port weld. Dr. Miller tested the question raised by Kasbekar: whether an MVE 808 tank, with a fully compromised vacuum seal, will experience that high of a rate of LN2 boil-off. The result established that Kasbekar's assumption (14 inches of LN2 boils off in approximately 22 hours) is simply false. Rather, even with a full vacuum seal loss, LN2 only boils off at only approximately .5 inches per hour. (Ringel Decl. Supp. Mot. Exclude Kasbekar, Ex. H ("Miller Report") at 19, ECF No.647-18).[3] Kasbekar has offered no scientific analysis to the contrary.

Second, Kasbekar's hypothesis that a complete vacuum seal failure can exist on an MVE 808 tank without exhibiting visible signs is also false. Cryogenic vessels will exhibit visible signs of significant frosting and condensation when the vacuum seal is compromised. However, every PFC employee denied observing such signs of vacuum seal failure from February 15 leading up to March 4, 2018. (Ringel Decl. Opp. Pls. Mot., Ex. E ("Cirimele Dep. I") at 69-74, ECF No. 669-10; Ex. I ("Lamb Dep.") at 28, ECF No. 668-05; Ex. L ("Popwell Dep.") at 119, 121, 123, 129, ECF No. 669-20). Thus, Dr. Miller analyzed the visual appearance of the exemplar tank during the boil-off test and confirmed that cryogenic vessels exhibit visible signs when vacuum seal is compromised. Kasbekar has offered no scientific analysis to the contrary. Because Kasbekar's causation opinion is connected to the scientific data – how fast LN2 boils-off and Tank 4's appearance – by only his word and not validating testing, the Court should exclude him under *Daubert*.

Plaintiffs' critiques of Dr. Miller's exemplar testing are unavailing and, in any event, cannot serve as a basis to prop up Kasbekar's otherwise untested causation opinion. Plaintiffs conveniently fail to inform the Court that Dr. Miller provided Plaintiffs with the analysis and

[3] Moreover, if, for argument's sake, Popwell's testimony were accurate, then 4 inches of LN2 would have remained in Tank 4 when Conaghan opened it on March 4. (Miller Report at 20, ECF No.647-18). There is no dispute in this case that 4 inches of LN2 in Tank 4 would have adequately stored Plaintiffs' tissue samples.

calculations that confirm his exemplar tank would have imploded just like Tank 4. (Ringel Decl. Supp. Def. Mot. Exclude Kasbekar, Ex. I ("Miller Rebuttal II") at 19, ECF No.647-20; Ex. K ("Miller Dep I") at 50:5-13, 176:5-14, ECF No. 669-18). The problem for Plaintiffs is that Dr. Miller's testing demonstrates that even with a complete vacuum seal failure, MVE 808 tanks do not lose LN2 fast enough to cause damage to tissue in less than 24 hours.

A final point is worth mentioning. Plaintiffs' tissue was removed by PFC before Tank 4 imploded late in the day on March 4, 2018. It is also undisputed that only after Tank 4 imploded, a crack in the tank's fill tube port's weld was first observed. But this does not mean the crack existed beforehand, let alone that it prompted a total vacuum seal loss prior to implosion. Plaintiffs acknowledge as much by stating, "it is impossible to even know how large the crack was at the time because the resulting implosion changed the crack size geometry." (Pls.' Opp. at 18). By the same logic, "it is impossible" for Kasbekar to reliably "know" that any crack existed at all before "the time" Tank 4 was discovered to be extremely low on LN2 when PFC (Dr. Conaghan) opened its lid around 12:30 pm on March 4. As a result, the mere existence of a crack found after-the-fact does not validate Kasbekar's causation opinion – that the crack existed beforehand and caused a vacuum seal failure which in turn rapidly diminished Tank 4's LN2 level to a point beyond capacity to safely store Plaintiffs' tissue.

C. **Kasbekar did not reliably rule out the obvious non-defect cause of the Plaintiffs' damages**.

In this section of their opposition, Plaintiffs continue to couch Kasbekar's analysis in terms of metallurgy and cracks. Their continued silence on the cryogenic aspect of his causation opinion is telling. Kasbekar did not address, let alone rule out, that Tank 4 simply ran dry of LN2 prior to the events in question. That Kasbekar looked for but did not find another crack inside of Tank 4 after-the-fact is immaterial to how fast LN2 boils off. After PFC unplugged Tank 4's controller on February 15, 2018 and initiated manual filling of Tank 4 with LN2, maintenance of sufficient LN2 to safely store Plaintiffs' tissue was entirely dependent on PFC's actions and the science of LN2 boil-off rates. Kasbekar's "analysis" avoids these issues. Therefore, Plaintiffs' argument that

Kasbekar accounted for the "potential alternative causes" of Plaintiffs' damages is without merit and should be rejected.

D. Kasbekar's flawed and untimely FEA should be excluded.

Plaintiffs' argument that Kasbekar used proper inputs for his FEA is nothing but a regurgitation of Kasbekar's own "say-so" that he is correct. Neither Plaintiffs nor Kasbekar have pointed to objective scientific data to confirm the numbers he used for his FEA are appropriate given the properties of the materials at issue under cryogenic conditions. Plaintiffs' hold the burden to establish Kasbekar's work has a reliable scientific foundation. Nothing in either *Daubert* or Rule 702 "requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146. Because Kasbekar offers nothing but his own flawed say-so that the fill line tube data he used is proper, his FEA outputs are not admissible. (*See also* Miller Rebuttal II at 2-3, ECF No.647-20).

Turning to the untimeliness of the disclosure, Plaintiffs offer excuse after excuse for why Kasbekar did not complete the FEA earlier. Kasbekar is Plaintiffs' sole engineering expert and was hired to provide design and manufacturing defect *and causation* opinions. The point Plaintiffs miss is that, because this is a product liability case, they hold the burden of proof. It is inappropriate for the plaintiff's expert in this type of case to hold back on conducting all of the work necessary to satisfy that burden in hopes that the defendant will not challenge him on the fundamentals of the opinion. Kasbekar did not do the FEA work until ***after*** he had already rendered the opinion that Tank 4's fill line tube weld was insufficiently robust. That cart-before-the-horse approach is the exact opposite of what *Daubert* and the scientific method demand. *See Claar v. Burlington N. R. Co.,* 29 F.3d 499, 502–03 (9th Cir. 1994) ("Coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method."); *Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 785 (10th Cir. 1999) ("Instead of reasoning known facts to reach a conclusion, the experts … reasoned from an end result in order to hypothesize what needed to be known but what was not.").

Kasbekar's untimely FEA a classic example of an expert that starts with the conclusion necessary for his client's case and then does the work to bolster his opinion after it was already disclosed. Kasbekar's piecemeal disclosure of support for his opinions is also contrary to Rule 26(a)(2)(B)(i). That rule plainly requires the original expert report to contain "all" of the opinions and "the basis and reasons for them." Plaintiffs' argument that there is no harm is belied by the fact that Plaintiffs do not dispute the cascade of events that followed the late disclosure.

The game Plaintiffs are trying to play by claiming Kasbekar only decided to do an FEA after Chart's expert, Ron Parrington, disclosed his opinions is too cute by half. Because Chart is not required to either disclose or call any experts at trial to prevail in this case, Plaintiffs and Chart are in different positions. In this respect, Plaintiffs' reliance on *Estate of Goldberg v. Goss-Jewett Co., Inc.*, 2019 WL 8227387 (C.D. Cal. Oct. 29, 2019) is misplaced. The court in *Estate of Goldberg* permitted a defendant's expert's late rebuttal, however, there was no indication that the outcome would have been the same had the plaintiff's expert waited so late to disclose a core basis of his opinion. Because Kasbekar's FEA was not disclosed by the November 6, 2020 expert report deadline, it should be excluded from this case under Rule 37(c).

II. WININGER'S OPINIONS SHOULD BE EXCLUDED AS UNRELIABLE AND IRRELEVANT.

In their opposition brief, Plaintiffs concede that Wininger's experience with computer controlled cryogenic vessels, like the MVE 808, is limited. (Pls. Opp. at 25:25-27, ECF No. 673-06). Plaintiffs also concede that Wininger did not consider alternative explanations or PFC's actions leading up to the incident. (*Id*. at 28:12-13). Plaintiffs claim, however, that Wininger's lack of experience with computer controlled cryogenic tanks is irrelevant because the controller was unplugged prior to the incident, thus not in use. They also claim that Wininger does not need to consider the facts surrounding the incident (e.g., alternative explanations and PFC's actions) because he is not opining as to PFC's safety expectations, he is opining as to an ordinary user's expectations. Plaintiffs' arguments are unavailing.

Plaintiffs' argument fails to appreciate that the ability of the MVE 808 to safely maintain cryogenic temperatures is intertwined with the proper use of the product and operation of its fail

safe designs, including the controller affixed to the tank. Plaintiffs' argument also assumes, without support, that the consumer expectation test is applicable. It is not. The consumer expectations test does not apply if a complex product is one which ordinary consumers may not otherwise have widely held minimum safety expectations. As noted by the California Supreme Court, "'[i]n many situations … the consumer would not know what to expect, because he would have no idea how safe the product could be made."' *Barker v. Lull Eng'g Co.,* 20 Cal.3d 413,430 (1978); *see also Bates v. John Deere, Co.,* 148 Cal.App.3d 40, 52 (1983).

All parties and experts agree that the MVE 808 and TEC3000 controller are sophisticated products. The fact that Wininger has no prior experience with an MVE 808 and TEC 3000, and no familiarity with computer controlled cryogenic tanks in general, emphasizes the complex nature of the products in question. It also reveals that the tank at issue is not a commonplace piece of equipment or part of the "everyday experience" of the consuming public, let alone the everyday experience of a lab director like Wininger. The general public, represented by the ordinary consumer, does not have minimum safety expectations regarding the use of the MVE 808 and TEC3000 controller. *Soule v. Gen. Motors Corp.*, 8 Cal.4th 548, 563 (1994).

The complexity of the MVE 808 is further demonstrated by the countless product-related considerations and design features alleged as impacting the incident. For example, liquid nitrogen supply, liquid nitrogen boil-off rates, liquid nitrogen levels, the controller, the controller alarms, the controller auto-fill function, annular fill lines, the getter, the vacuum insulation, and the thickness of welds. The parties have retained experts in metallurgy, cryogenic engineering, and biomechanics to dissect the issues presented. Their long and detailed analysis of technical aspects of the MVE 808 and TEC 3000 controller further underscore the inappropriateness of the consumer-expectations test.

Moreover, the facts and circumstances of the incident add to the intricacies of this case. The MVE 808 was misused in several ways, including PFC disabling its fail safe features and PFC's failure to comply with its laboratory quality management (QM) plan concerning liquid nitrogen levels and operation of the controller. It is worth noting that PFC's laboratory director admitted the lab did not comply with its own QM procedures and the College of American

Pathologists also found PFC in violation of such procedures. (Ringel Decl. Opp. Pls. Mot. Exclude, Ex. D ("Conaghan Dep. II") at 82:5-6, 153:20-154:2, 154:17-19, 155:3-5, 158:11-21, ECF No. 669-08)(Zeman Decl. Supp. Pls. Mot. Exclude, Ex. 13 ("3/11/18 CAP Letter"), ECF No. 630-16). The recurrent misuse caused the ultimate loss of vacuum seal leading to the Plaintiffs alleged injuries. Wininger cannot opine as to the use of the MVE 808 without considering PFC's actions. Nor could he ever provide a valid opinion on the safety expectations of the MVE 808 without considering and acknowledging that PFC was operating it after February 15, 2018 with the controller unplugged and disabled. When assessing the applicability of the consumer expectation test, the critical question is not whether the product, when considered in isolation, is beyond the ordinary knowledge of the consumer, but whether the product, *in the context of the facts and circumstances of its failure*, is one about which the ordinary consumers can form minimum safety expectations." *McCabe v. Am. Honda Motor Co.,* 100 Cal.App.4th 1111, 1124 (2002) (citing *Soule*, 8 Cal.4th at 568-569; emphasis in original). Consideration of the foregoing factors, compiled with the complex nature of the product itself, stresses the unordinary circumstances of this case. Thus, the consumer expectation test is not applicable. Wininger's testimony regarding the same is irrelevant, unreliable, and will not help the trier of fact in any meaningful manner.

III. GRILL'S OPINIONS SHOULD BE EXCLUDED AS SHE EMPLOYED AN UNRELIABLE METHODOLOGY AND FAILED TO FOLLOW THE STANDARD OF CARE.

Chart's argument to exclude Grill is straightforward: by failing to perform any objective testing and structured clinical interview, Grill's opinions lack any indicia of scientific reliability and should therefore be excluded. This argument is consistent with the Ninth Circuit holding in *U.S. v. Finley*, 301 F.3d 1000, 1011 (2002). In *Finley*, the Court rejected the argument Plaintiffs' make here. The *Finley* court distinguished between an expert opinion that recites "the allegation of the alleged victim in the guise of a medical opinion" and an expert opinion that "incorporates testing, case history, interviews with the patient and family, medical factors, and expert experience applying the information contained in the DSM-IV and other mental health publications." *Id*. at 1012. The court determined that the latter opinion is reliable and admissible, whereas the former

opinion is unreliable and should be excluded. Additionally, as Plaintiffs point out, the expert in *Finley* was a clinical psychologist, not a practicing forensic psychologist. Thus, the *Finley* standard applies to evaluations by clinical psychologists. This is in line with Chart's position that Grill's methodology is inadequate under both clinical and forensic psychology standards.

Moreover, Chart's position is also consistent with the standard in the scientific community. Dr. Lawson's expert rebuttal report outlines the multitude of errors in Grill's methodology and her deviation from the standard of care. Plaintiffs have failed to rebut this. Instead, Plaintiffs manipulate Dr. Lawson's opinions regarding the "gold standard for psychologists." (Pls. Opp. at 30:12-14, ECF No. 673-06). Contrary to Plaintiffs' claims, Dr. Lawson opined that a *structured diagnostic interview* is the "gold standard" as it "reduces the error introduced by idiosyncratic idiopathic procedures almost to zero." (Ringel Decl. Supp. Mot. Exclude Grill, Ex. D ("Lawson Report") at 4, ECF No. 641-10) (emphasis added). A reliable structured interview involves "identical questions in a fixed sequence to assess empirically validated categories of psychiatric distress (e.g., Major Depressive Disorder, Posttraumatic Stress Disorder)." *(Id.)*. A thorough forensic evaluation requires a significant time commitment, which generally includes a minimum of 2-3 hours of psychological testing with the administration of multiple measures that assess for malingering; three or more hours of in-depth psychosocial history interview; and two or more hours of differential diagnostic interviewing. (*Id*. at 12, fn 24). Grill's brief 1.5 to 2 hour Zoom interviews do not meet this standard.

Plaintiffs do not present any case law to support a contrary finding. Instead, they present unpersuasive and non-binding decisions. For example, Plaintiffs cite to *Kanellakopoulous v. Unimerica Life Ins. Co*., 2018 WL 984826, *3 (N.D. Cal. Feb. 20, 2018) for the proposition that expert testimony by a clinical psychologist is reliable if it has a reliable basis in the knowledge and experience of the expert's field. (Pls. Opp. at 29:21-26, ECF No. 673-06). *Kanellakopoulous* is distinguishable as the psychologist "had no choice but to rely on Plaintiff's medical records to evaluate his alleged catastrophic disability given plaintiff's assertion that the catastrophic disability terminated before he filed his insurance claim and before the lawsuit was filed." *Id*. It was therefore impossible for the psychologist to analyze the plaintiff's condition outside reviewing medical

records and relying on his experience. That is not the case here. Accordingly, Grill's opinions should be excluded.

CONCLUSION

For the foregoing reasons, Chart respectfully requests that this Court grant its Motion to Exclude Plaintiffs' Experts Anand Kasbekar, David Wininger, and Elizabeth Grill.

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Respectfully submitted,

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